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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,333	01/27/2006	Gilad Lavi	S2082/20004	4212
3000 7590 11/02/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER ANDERSON, MICHAEL J	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 11/02/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary

Application No.

10/566,333

Applicant(s)

LAVI ET AL.

Examiner

Michael J. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 9, 38, 44, and 45 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over Chevallier (US patent publication No. 2002/0193746 A1) (Chevallier) and/or Jansen (US patent 6,319,233) (Jansen) in view of Gilbert (US patent No.7,097,634) (Gilbert).

With regard to claim 1, 9, 38, 44, and 45 Chevallier discloses (abstract; figures 1-8) an injection device (figures 1) comprising: a housing (10) having a proximate end and a distal end, the distal end having an opening therein; a shield (16, 18) slideably coupled to the housing at said distal end thereof; a cartridge barrel (A) within the housing, the cartridge barrel having proximate and distal ends; a needle (14) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (12) within the cartridge barrel; a driver (12) coupled to the stopper; a spring (30, 32, 22) coupled between the housing and the driver; a driver trigger (12, abstract) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable in use to release

the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (abstract). Chevallier does not disclose the cannula being disposed within said shield prior to activation of said device. Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Gilbert to make the safety shield protection prior to injection.

Furthermore, with regard to claim 1, 9, 38, 44, and 45 Jansen discloses (abstract; figures 1-19) an injection device (10) comprising: a housing (26) having a proximate end and a distal end, the distal end having an opening therein; a shield (28) slideably coupled to the housing at said distal end thereof; a cartridge barrel (16) within the housing, the cartridge barrel having proximate and distal ends; a needle (18) cannula fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end; a stopper (20) within the cartridge barrel; a driver (22) coupled to the stopper; a spring (30) coupled between the housing and the driver; a driver trigger (48, 58) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable in use to release the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism for releasing

the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield and urges the shield away from the housing so as to cover the needle cannula (columns 2, 4, and 6). Jansen does not disclose the cannula being disposed within said shield prior to activation of said device. Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Jansen as disclosed by Gilbert to make the safety shield protection prior to injection.

Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70 19-21, 50-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier (US patent publication No. 2002/0193746 A1) (Chevallier) and/or Jansen (US patent 6,319,233) (Jansen) in view of Lavi (US patent publication 2003/0105430) (Lavi) and/or Marshall (US patent No. 5,599,309) (Marshall)) and further in view of Gilbert (US patent No.7,097,634) (Gilbert).

With regard to claim 2, 8, 19-21, 50-52, and 58-59, Chevallier and Gilbert disclose an injection device according to claim 1 however, Chevallier may not disclose a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield. Lavi (figures 37-47) and Marshall (abstract, figure 1, and 6-9) discloses a means for allowing the driver to drive the cartridge barrel through the housing following activation of said driver trigger and prior to movement of the stopper through the

cartridge barrel, thereby urging the needle cannula outward relative to the housing and shield (abstracts). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

With regard to claims 3-7, 10-15, 35-37, 46-48, 61, 63-64 and 70, Chevallier and Gilbert disclose an injection device according to claims 1 and 9. However, Chevallier may not disclose the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger. Marshall discloses (abstract, figure 1, and 6-9) the driver trigger being coupled to said shield, wherein movement of the shield inwardly with respect to the housing activates the trigger. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Marshall to make the safety shield injection syringe automated.

With regard to claims 16-18, 53-57, 60, 22-25, 39-42, 26, 28-31, 49, 65-66, 69, 27, 62, 32-34, 43 and 67-68, Chevallier or Jansen and Gilbert disclose an injection device according to claim 9 however, Chevallier or Jansen may not disclose a set of supports, injector rods, safety tabs, injector cartridge and viewing window. Lavi (shows in figures 37-47 an injection device with a housing (304), a shield (302), a cartridge barrel (204) with a needle cannula (32), a stopper (38), a driver (208), a spring (20), a driver trigger (24), a release mechanism (48+56) and a titration rod (234)) and Marshall (abstract, figure 1, and 6-9) disclose a set of supports, injector rods, safety tabs, injector

cartridge and viewing window. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier or Jansen as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated.

Response to Amendment

The present communication responds to the Amendment of 08/20/2007. By this communication, Claims 1, 9, 21, 31, 38, 44 and 45 have been amended. The amendments did not add new matter. Claims 1-70 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments with respect to claims 1-70 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's arguments of 1, 9, 38, 44, and 45, Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device and further discloses the syringe is automated.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's arguments of 2, Gilbert discloses (column 1, lines 20-50) the cannula being disposed within said shield prior to activation of said device and further discloses the syringe is automated.

In response to applicant's arguments of claim 3, Jenson discloses a moving shield.

In response to applicant's arguments of claim 17, about the showing of a driver that includes a set of barrel supports. Bitdinger (US Patent No. 5,478,316 form references cited) discloses as early as 1995 the use of a driver (58) system in an injector pen. Marshall (14 and 15), Jenson (20 and 22), Lavi and others all disclose a driver system.

In response to applicant's arguments of claim 18, that the cartridge barrel supports are adapted to detect the end of the barrel and release the driving unit. At least Lavi discloses this feature.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson

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Examiner
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MJA
10/27/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons